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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 9 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Via Federal Express

WARNING LETTER

Mr. Robert Chester
Breath of Life
100 McFaul Way
P.O. Box 31
Zephyr, Cove, NV 89448-0031

Dear Mr. Chester:

During an inspection of [REDACTED] located in [REDACTED] between December 12, 1995, and March 4, 1996, our investigator learned that [REDACTED] is distributing the Breath of Life Manual Resuscitator, Adult/Child model and Infant/Toddler models device without a prescription. Your labeling also suggests that the device may be distributed to the lay person without a prescription. The Breath of Life Emergency Manual Resuscitator (TM) and Breath of Life Resuscitator Kits (Kits) are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The Food and Drug Administration regards manual emergency ventilators as prescription devices since adequate instructions for use by lay persons cannot be written. Our review of the 510(k) files does not present evidence that the Breath of Life Manual Resuscitator and Resuscitator Kits were cleared for marketing direct to consumers as over the counter (OTC) devices.

We have determined that these devices are misbranded and adulterated within the meaning of Section 502(f)(1), 502(o), and 501(f)(1)(B), of the Act as explained below.

The devices are misbranded within the meaning of Section 502(f)(1) in that their labeling fails to bear adequate directions for use for the purpose for which they are intended, that is, manually resuscitating a person who is not breathing. This is because these are prescription devices, for which, by definition in Title 21 Code of Federal Regulations, Section 801.109, adequate directions for use by a lay person cannot be written. A lay person may not appropriately use the [REDACTED]. If used inappropriately, inadequate pressure may be delivered with the result that adequate ventilation is not

provided to a patient in cardiac arrest, a condition in which lung compliance may be low. The proper assessment of lung compliance using a Resuscitator is difficult and directions for use cannot be written for the lay person.

A 510(k) is required when changes are made that could significantly affect the safety and/or effectiveness of the device or when there is a major change in intended use (e.g. your change from prescription to OTC). In the case of Breath of Life, the following technical changes were made which could affect safety and effectiveness:

1. The kit which is being distributed includes a [REDACTED] intended to make the product reusable, while the previously cleared Resuscitators were intended for single use; and,
2. The [REDACTED] in the currently distributed device is located in the [REDACTED] while the previously cleared models contain a [REDACTED] located on [REDACTED].

In the first instance, the appropriate processes that provide for reuse of medical devices need to be supported by data that demonstrate that the product will continue to function as intended beyond the first use and that no new problems, such as potential bioburden in this case, result from the change or that such problems have been adequately addressed. In the case of the second technological change, the pressures being delivered to the lung may be directly affected by this change. Data should be submitted to support this type of change demonstrating that the modified device remains substantially equivalent to its predicate.

Therefore, the marketed Breath of Life Resuscitators and Kits, both Adult and Children model and Infant and Toddler model, are misbranded within the meaning of Section 502(o) of the Act in that a notice or other information respecting the devices was not provided to the FDA as required by Section 510(k). In effect, we believe the Breath of Life Resuscitators and Kits, both Adult and Children and Infant and Toddler models, are new devices which require the submission of a new 510(k). All of the technical changes and issues, including distribution as OTC, would need to be supported by appropriate data in a new 510(k).

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You have been previously notified of this determination by letter dated August 26, 1996, from the Center for Devices and Radiological Health's Office of Device Evaluation. The letter informed you that you had changed your devices significantly and that you are required to submit a new 510(k) because of these revisions.

Until this device is determined by FDA to be substantially equivalent, it is automatically classified by statute as a Class III Device. Therefore, the Breath of Life Resuscitators and Kits, both Adult and Children model and Infant and Toddler model, are adulterated within the meaning of Section 501(f)(1)(B) in that they are Class III devices under Section 513(f) and do not have an approved application for premarket approval in effect pursuant to Section 515(a) or an approved application for an investigational device exemption under Section 520(g).

As previously discussed and documented by FAX, representing your devices as "the only Emergency Manual Resuscitator approved for use by the general public per FDA 510(k)" is misleading. That misleading representation constitutes misbranding within the meaning of the Act (Title 21 Code of Federal Regulations Section 807.97). The statement creates an impression of official approval by alleging compliance with the premarket notification regulations. Also, as previously indicated, FDA did not clear the Resuscitators for use by the lay person. We acknowledge that you have agreed to discontinue making such representations regarding your devices.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all requirements of the Act and regulations promulgated there under are being met. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this into account when considering the award of contracts.

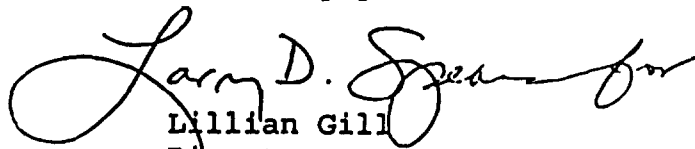
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include but are not limited to seizure, injunction, and/or civil penalties.

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Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, 2098 Gaither Road, HFZ-343, Rockville, Maryland, 20850, to the attention of Mary Donoghue, M.P.H.

Sincerely yours,



Lillian Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

cc: [REDACTED]
[REDACTED]
[REDACTED]

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